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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,985	02/09/2004	Robert A. Rabiner	18554-035001	9583

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EXAMINER

SHAHRESTANI, NASIR

ART UNIT	PAPER NUMBER
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3737

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04/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/774,985	Applicant(s) RABINER ET AL.	
	Examiner NASIR SHAHRESTANI	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-12, 14, 15, 17-27, 29, 30, 32, 64-70 and 72-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-12, 14-15, 17-27, 29-30, 32, 64-70, 72-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/21/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is responsive to Applicant's communication filed 2/21/2008.

Claims 1-3, 5-12, 14-15, 17-27, 29-30, 32, 64-70, 72-78 are pending.

Response to Arguments

Applicant's arguments filed 2/21/2008 have been fully considered but they are not persuasive. Applicants argue that the references Wuchinich, Sakurai, Weng, and Kuris, taken alone and in combination, fail to disclose or suggest a probe that is configured such that cavitation is produced, in a medium surrounding the probe, along a portion of the probe having a radially asymmetric cross section, when the portion of the probe having the radially asymmetric cross section torsionally vibrates during use.

Examiner respectfully points out that the applicants arguments would be valid if the claims were directed towards a method and since the claims are presented as "an ultrasonic medical device", functional language does not overcome the prior art which teaches all the components of the claimed limitations. Applicants intended use is not sufficient to overcome the prior art.

Applicant's arguments with respect to said claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6-7, 9-11, 17, 19-22, 25-26, 32, 64-66, 68-69, 72-73, 76-78, are rejected under 35 U.S.C. 103(a) as being unpatentable over Wuchinich (U.S. 2001/0047166) in view of Sakurai et al (U.S. 2003/0045887), and further in view of Weng et al. (U.S. 5,269,297).

Wuchinich discloses an ultrasonic medical device that creates torsional vibration (figure 4, element 40); a probe comprising a proximal end coupled to a transducer (figure 1, element 1), a distal end, with a longitudinal axis between (figure 4), with an energy source engaged to the transducer producing ultrasonic energy (figure 1, elements 1 and 15); torsional vibration, which by definition rotates and counter-rotates the ultrasonic probe, propagates the length of the probe through the resonator resulting in a plurality of nodes (paragraph 12), which inherently result in a plurality of anti-nodes at half the distance between any two nodes. In the embodiment shown in figure 3, the longitudinal axis of the probe has a radially asymmetric cross section (figure 3, element 41). It is also possible for the axis to have an approximately rectangular cross section (paragraph 70) or have longitudinal grooves, which create a plurality of “flutes”, or projections, extending along the length of the probe (paragraph 10). Additionally, the diameter of the probe can be tapered or varied from the proximal end to the distal end of the probe (figure 4).

Wuchinich, as discussed above, substantially discloses the invention as claimed, however fails to explicitly disclose operating at the resonant frequency of the transducer.

Sakurai also discloses an ultrasonic probe capable of torsional vibration and teaches that “resonance-point tracking” is possible in order to set the resonance frequency to the frequency of the vibration oscillator (paragraph 77). Additionally, the elongated probe of the ultrasound device has an approximately circular cross section (figure 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Wuchinich with the teachings of Sakurai to increase the efficiency of the device.

Wuchinich in view of Sakurai et al. does not teach production of cavitation.

Weng et al. teach an ultrasonic transmission apparatus wherein the distal segment (element 16b) undergoes displacement at ultrasonic frequencies and driving the tip (element 18) at ultrasonic frequencies and producing cavitation (col. 14 lines 40-46).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have modify the device as disclosed by Wuchinich in view of Sakurai et al. and to have further included means for the ultrasonic probe to produce cavitation along the longitudinal axis in a medium surrounding the probe during use in order to destroy a thrombus in the patient’s blood vessel. Furthermore, it would have been an obvious modification to one ordinary skill in the art to further include means for optimized energy propagation for the ultrasound transducer.

Claims 5 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wuchinich in view of Sakurai, in further view of Weng as applied to claims 4 and 19, respectively, above, and further in view of Rabiner et al (US 2002/0029054).

Art Unit: 3737

Wuchinich in view of Sakurai, in view of Weng et al., substantially discloses the invention as claimed. However, the references do not explicitly teach that the ultrasonic probe can be used to ablate biological material along the portion of the longitudinal axis comprising the radially asymmetric cross section.

Rabiner et al. teach that it is advantageous to use ultrasonic vibration along the longitudinal axis of an ultrasonic probe to destroy tissue along the length of the probe (par. 26) using cavitation in order to be less traumatic to surrounding tissue.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Wuchinich in view of Sakurai, and Weng et al. in light of the teachings of the reference by Rabiner et al. to provide decreased procedure time and less residual tissue damage (paragraph 26).

Claims 8, 12, 14-15, 24, 27, 29-30, 67, 70, are rejected under 35 U.S.C. 103(a) as being unpatentable over Wuchinich in view of Sakurai, in view of Weng et al. and further in view of Fenton (U.S. 2003/0212331).

Wuchinich in view of Sakurai and in further view of Weng et al. substantially discloses the invention as claimed, however fail to disclose the capability for flexibility of the probe and fail to explicitly disclose the operating frequency range of the device.

Fenton discloses an ultrasonic device capable of torsional vibration, which states that ultrasonic surgical instruments typically operate in the range of 20 to 100 kHz (paragraph 4). In addition, the vibration element of the probe disclosed in the reference by Fenton is “formed of a flexible, compliant material” which may “have a substantially curvilinear configuration”

(paragraph 19). In another embodiment the probe has a substantially uniform cross section (figure 2A).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Wuchinich in view of Sakurai, in further view of Weng et al. in light of the teachings of Fenton, as flexibility and a curved shape in the probe allow the probe to reach a greater number of areas minimally invasively.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wuchinich in view of Sakurai, in further view of Weng et al., and further in view of Jones (U.S. 6,433,464).

Wuchinich in view of Sakurai, in further view of Weng et al. substantially disclose the invention as claimed but fail to teach that the device may be disposable.

Jones discloses a device for dissolving and removing unwanted biologic materials using acoustic waves and teaches one advantage of the device is that it is optionally disposable (col. 18, lines 59-67).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Wuchinich in view of Sakurai, in further view of Weng et al. with the teachings of Jones in order to make the probe disposable in order to provide a device that is more convenient to use and does eliminating the need for cleaning or sterilization.

Claims 74-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wuchinich in view of Sakurai, in further view of Weng et al., and further in view of Hood (U.S. 5,935,142).

Wuchinich in view of Sakurai, in further view of Weng et al. substantially disclose the invention as claimed, however fail to teach wherein a length of the probe is substantially equal to an integer multiple of a one-half wavelength of a torsional resonance of the transducer.

Hood teaches a cavitation-assisted method of material separation wherein the enlarged section (element 134) has a length equal to approximately a half wavelength with an anti-node positioned generally at the longitudinal center of the enlarged section.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Wuchinich in view of Sakurai, in further view of Weng et al. with the teachings of Hood in order to provide for optimal cavitation that would in turn provide for breakage of various thrombi.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NASIR SHAHRESTANI whose telephone number is (571)270-1031. The examiner can normally be reached on Mon.-Thurs: 7:30-5:00, 2nd Friday: 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3737

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L Casler/
Supervisory Patent Examiner, Art Unit
3737

/N. S./
Examiner, Art Unit 3737